

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

FOREST LABORATORIES, INC., )  
FOREST LABORATORIES HOLDINGS, LTD., )  
MERZ PHARMA GMBH & CO. KGAA, and )  
MERZ PHARMACEUTICALS GMBH, )

Plaintiffs,

v.

COBALT LABORATORIES INC., LUPIN )  
PHARMACEUTICALS, INC., LUPIN LTD., )  
ORCHID PHARMACEUTICALS INC., ORCHID )  
CHEMICALS & PHARMACEUTICALS LTD. )  
(d/b/a ORCHID HEALTHCARE), TEVA )  
PHARMACEUTICALS USA, INC., UPSHER- )  
SMITH LABORATORIES, INC., WOCKHARDT )  
USA INC., and WOCKHARDT LIMITED, )

Defendants.

C.A. No. 08-21-GMS

**DEFENDANT ORCHID PHARMACEUTICALS INC.'S ANSWER**

Defendant Orchid Pharmaceuticals, Inc. ("Orchid Pharma") hereby answers the Complaint of Plaintiffs Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH ("Plaintiffs") as follows:

**PARTIES<sup>1</sup>**

1. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1 of the Complaint, and therefore denies the allegations of paragraph 1 on that basis.

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<sup>1</sup> To facilitate the Court's comparison of the allegations in the Complaint and defendant's responses thereto, Orchid has incorporated modified Headings that appear in the Complaint. It should be understood, however, that Orchid does not necessarily agree with characterizations in such Headings and, indeed, does not waive any rights to object to such characterizations or their implications.

2. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 of the Complaint, and therefore denies the allegations of paragraph 2 on that basis.

3. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 of the Complaint, and therefore denies the allegations of paragraph 3 on that basis.

4. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the Complaint, and therefore denies the allegations of paragraph 4 on that basis.

5. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 5 of the Complaint, and therefore denies the allegations of paragraph 5 on that basis.

6. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 6 of the Complaint, and therefore denies the allegations of paragraph 6 on that basis.

7. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 7 of the Complaint, and therefore denies the allegations of paragraph 7 on that basis.

8. Orchid Pharma denies the allegations of paragraph 8 of the Complaint, except that Orchid Pharma admits that its is a Delaware corporation and a wholly-owned subsidiary of Defendant Orchid Chemicals & Pharmaceuticals Ltd.

9. Orchid Pharma denies the allegations of paragraph 9 of the Complaint, except that Orchid Pharma admits that Defendant Orchid Chemicals & Pharmaceuticals Ltd. is an Indian

corporation having a place of business at Orchid Towers, 313 Valluvar Kottam High Road, Nungambakkam, Chennai, Tamil Nadu 600 034 India and a place of business at Plot No. B3-B6 & B11-B14, SIPCOT Industrial Park, Irungattukottai, Sriperumbudur, Kancheepuram District, 602 105 India, and that Defendant Orchid Chemicals & Pharmaceuticals Ltd. manufactures generic drug products.

10. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 10 of the Complaint, and therefore denies the allegations of paragraph 10 on that basis.

11. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 11 of the Complaint, and therefore denies the allegations of paragraph 11 on that basis.

12. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 12 of the Complaint, and therefore denies the allegations of paragraph 12 on that basis.

13. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13 of the Complaint, and therefore denies the allegations of paragraph 13 on that basis.

#### **NATURE OF THE ACTION**

14. In responding to paragraph 14, Orchid Pharma admits that the Complaint purports to state claims for infringement of United States Patent No. 5,061,703 ("the '703 patent"), which are based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, but Orchid Pharma denies any liability or wrongdoing whatsoever.

**JURISDICTION AND VENUE**

15. In responding to paragraph 15, Orchid Pharma admits that the Complaint alleges that this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), but Orchid Pharma denies any liability or wrongdoing whatsoever.

16. Orchid Pharma denies each and every allegation and/or legal conclusion contained in paragraph 16 of the Complaint.

17. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17 of the Complaint, and therefore denies the allegations of paragraph 17 on that basis.

18. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 18 of the Complaint, and therefore denies the allegations of paragraph 18 on that basis.

19. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 19 of the Complaint, and therefore denies the allegations of paragraph 19 on that basis.

20. Orchid Pharma admits that this Court has personal jurisdiction over Orchid Pharma because Orchid Pharma is a Delaware corporation. Orchid Pharma denies any remaining allegations in paragraph 20 of the Complaint and denies any liability or wrongdoing whatsoever.

21. Orchid Pharma denies each and every allegation and/or legal conclusion contained in paragraph 21 of the Complaint.

22. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22 of the Complaint, and therefore denies the allegations of paragraph 22 on that basis.

23. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23 of the Complaint, and therefore denies the allegations of paragraph 23 on that basis.

24. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 24 of the Complaint, and therefore denies the allegations of paragraph 24 on that basis.

25. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 25 of the Complaint, and therefore denies the allegations of paragraph 25 on that basis.

26. Orchid Pharma denies the allegations of paragraph 26 of the Complaint, but with respect to itself admits that venue is proper in this judicial district pursuant to 28 U.S.C. § 1391.

#### **THE PATENT-IN-SUIT**

27. Orchid Pharma admits that United States Patent No. 5,061,703, titled “Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia,” states on its face that it was issued by the United States Patent and Trademark Office. Orchid Pharma denies that the ‘703 patent was “duly and legally issued” by the United States Patent and Trademark Office. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 27 of the Complaint, and therefore denies the remaining allegations of paragraph 27 on that basis.

28. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 28 of the Complaint, and therefore denies the allegations of paragraph 28 on that basis.

29. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 29 of the Complaint, and therefore denies the allegations of paragraph 29 on that basis.

30. Orchid Pharma admits that an ex parte reexamination certificate for the '703 patent indicates on its face that it was issued by PTO on November 7, 2006. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 30 of the Complaint, and therefore denies the remaining allegations of paragraph 30 on that basis.

**ALLEGED ACTS GIVING RISE TO THIS ACTION**

**Count I – Alleged Infringement of the '703 Patent by Defendant Cobalt**

31. – 36. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 31-36 of the Complaint, and therefore denies the allegations of paragraphs 31-36 on that basis.

**Count II – Alleged Infringement of the '703 Patent by Defendants Lupin and Lupin Pharma**

37. – 44. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 37-44 of the Complaint, and therefore denies the allegations of paragraphs 37-44 on that basis.

**Count III – Alleged Infringement of the '703 Patent by Defendants Orchid and Orchid Pharma**

45. Orchid Pharma denies each and every allegation and/or legal conclusion contained in paragraph 45 of the Complaint.

46. Orchid Pharma lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 46 of the Complaint, and therefore denies them.

47. Orchid Pharma denies each and every allegation and/or legal conclusion contained in paragraph 47 of the Complaint.

48. Orchid Pharma denies each and every allegation and/or legal conclusion contained in paragraph 48 of the Complaint.

49. Orchid Pharma each and every allegation and/or legal conclusion contained in paragraph 49 of the Complaint.

50. Orchid Pharma denies that it was aware of the '703 patent prior to the filing date of ANDA No. 90-044. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 50 of the Complaint, and therefore denies the allegations of paragraph 50 on that basis.

51. Orchid Pharma denies each and every allegation and/or legal conclusion contained in paragraph 51 of the Complaint.

52. Orchid Pharma denies each and every allegation and/or legal conclusion contained in paragraph 52 of the Complaint.

**Count IV – Infringement of the '703 Patent by Defendant Teva**

53. – 58. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 53-58 of the Complaint, and therefore denies the allegations of paragraphs 53-58 on that basis.

**Count V – Infringement of the '703 Patent by Defendant Upsher-Smith**

59. – 64. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 59-64 of the Complaint, and therefore denies the allegations of paragraphs 59-64 on that basis.

**Count VI – Infringement of the ‘703 Patent by Defendants Wockhardt  
and Wockhardt USA**

65. – 72. Orchid Pharma lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 65-72 of the Complaint, and therefore denies the allegations of paragraphs 65-72 on that basis.

**RESPONSE TO PRAYER FOR RELIEF**

73. Orchid Pharma repeats and realleges its responses to the allegations in paragraphs 1 through 72 of the Complaint as though fully set forth herein. The “WHEREFORE” paragraphs following paragraph 72 of the Complaint state Plaintiffs’ prayer for relief for which no response is required. To the extent a response is required, Orchid Pharma denies the allegations set forth in the “WHEREFORE” paragraphs and denies that Plaintiffs are entitled to any of the relief requested therein, or to any relief whatsoever.

**DEFENSES**

**First Defense**

**(Failure to State a Claim)**

74. Orchid Pharma repeats and realleges its responses to the allegations in paragraphs 1 through 73 of the Complaint as though fully set forth herein.

75. Orchid Pharma did not participate in, contribute to, or otherwise aid in the preparation of ANDA No. 90-044 or in its submission to the FDA.

76. Plaintiffs fail to state a claim against Orchid Pharma upon which relief may be granted. The allegations in the Complaint against Orchid Pharma should therefore be dismissed with prejudice.



**Second Defense**

**(Non-infringement)**

77. Orchid Pharma repeats and realleges its responses to the allegations in paragraphs 1 through 76 of the Complaint as though fully set forth herein.

78. Orchid Pharma does not infringe, has not infringed, and will not infringe (directly, indirectly, contributorily or by inducement) any valid and enforceable claim of the '703 patent.

**Third Defense**

**(Invalidity)**

79. Orchid Pharma repeats and realleges its responses to the allegations in paragraphs 1 through 78 of the Complaint as though fully set forth herein.

80. On information and belief, each and every claim of the '703 patent is invalid and void for failure to meet the requirements of Title 35, United States Code, including, *inter alia*, §§ 101, 102, 103, 112, 132, and 305.

Respectfully submitted,

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Dated: March 3, 2008  
852229 / 32657

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

I, Richard L. Horwitz, hereby certify that on March 3, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on March 3, 2008, the attached document was Electronically Mailed to the following person(s):

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